Dr. Mark McClellan's Remarks
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Thank you, Bruce (Roberts) for that introduction, and I also want to thank the NCPA executive Committee for inviting me here today. It's good to be back with all of you. I have a number of things I want to talk about today. I want to start with the importance of outreach to our beneficiaries around the new Medicare prescription drug benefit, because this is a really important part of making our health care system better. This is only going to work well if together we are able to make the most of leadership from the health professionals who have the most opportunity to have an impact – positive or negative – on the success of the Medicare prescription drug benefit and of our broader efforts to turn Medicare into an up-to-date, personalized, prevention-oriented health care program.

A while back, Bruce Roberts came to CMS and to talk about how he saw NCPA working with us to get seniors the help they need. It reminded me, again, how important pharmacists can be and must be if we are going to succeed in supporting a high-quality, patient-focused, efficient health care team. And this is Bruce's vision – that we work together to capitalize on the potential for tremendous value to our health care system through trusted and effective interactions between pharmacists and their patients. And we're in a position to do that through the Medicare drug benefit.

I want to tell you today that we are going to provide that drug benefit on schedule, everywhere in the country, in just eight months. That is in no small part due to the constructive input we've received from your representatives as we have proposed and finalized the regulations, and issued a broad range of guidances and instructions so that drug plans will know the approaches we are looking for to assure high-quality, broad access to medically necessary drugs and community pharmacy services, and through many other steps in what we've made sure is an extensive public and participatory and responsive prices. Now, I can tell you that in this process, I don't think we've made anyone completely happy – but I can tell you that we've listened and we'll continue to do so, in order to do the best possible job of both providing drug coverage to seniors and getting us to a better health care system that more clearly rewards and supports higher quality and lower costs and better value.

And working with you over the last few years, I've come to know how important – how essential – you all are to achieving this critical public health goal. So, I want to thank all of you, not only for your work on the front lines of getting better and more affordable drugs to our beneficiaries, but also on working to help us implement the new drug law and the changes it will bring – changes that undoubtedly will be more positive, the more you continue to be involved with us.

We intend to build on the foundation that Bruce Roberts and other pharmacy leaders, such as Tony Welder, Lonnie Wilson and Bruce Simmonsin have helped develop, so that we will take the next steps together. This is critical both because beneficiaries working with pharmacists that they know and trust is the best way to provide prescription drug assistance, and because, let's face it, the drug benefit is not only important new help to our beneficiaries. It's also an important new opportunity for pharmacies to reinforce the value and support that they provide to beneficiaries – to build up that patient trust, because you now have important new ways to make a difference in your patients' lives.

Based on everything we are seeing so far, it looks like we are on track for a positive impact. Our latest estimates, based on detailed actuarial and economic analysis of our specific implementation plans, are that the drug benefit will have a significantly positive financial impact on pharmacies. That includes an expected net increase in pharmacy revenues (of 0.6% to 1.9%), and the potential for positive overall sales impacts from increased foot traffic through the pharmacy.

But most importantly, the drug benefit has the potential to significantly enhance your role as an essential health care provider in Medicare – not only because you can help them take advantage of the drug benefit to better afford their medicines, but also because it provides you with new opportunities to move toward more efficient, electronic systems for providing prescriptions with fewer errors and lower administrative costs, and new opportunities to help beneficiaries save on less costly and safe medicines like generics, and because it gives you new opportunities to help beneficiaries manage their medications more effectively.

I am talking about these enhanced opportunities for pharmacists to improve the care while reducing the costs for individual patients because, as I've discussed with Bruce and many of you, this is an essential part of what the new Medicare law is really all about. The drug benefit itself is a really big example of how we are going to bring Medicare's benefits up to date and get them in line with modern medicine. For example, it makes no sense when it comes to patients with diabetes, for Medicare to pay for heart surgeries and limb amputations and dialysis but not the medicines and lifestyle counseling that have been proven to prevent the diabetes complications in the first place. In modern health care, drugs mean longer, higher-quality lives for patients. People have been talking about the sustainability of the Medicare program, and I want to tell you, the only sustainable foundation for Medicare is one that is up to date with modern medicine. You need up to date coverage to get up-to-date care that avoids the unnecessary health complications and costs that are adding many billions to our health care costs and preventing patients from getting up to date care. You can't build a sustainable, 21st century Medicare program without coverage for prescription drugs.

Through the drug benefit and through other changes happening right now in Medicare – like up-to-date coverage of preventive services, and new programs to

help beneficiaries with chronic illnesses get better coordination and support in preventing complications, and better information on the quality and costs of care, and new support for electronic health systems, and new ways of paying for care that pay for better quality not simply more services – through many changes like these, we are using the Medicare law to create a Medicare program that provides new support and new financial rewards for prevention-oriented, personalized, up-to-date medical care.

And you know what, we can't get there without building on the close relationships that pharmacists have developed with so many of America's seniors. Most Medicare beneficiaries regularly use prescription drugs, and they frequently come into contact with their local pharmacist. Pharmacists are the logical, and the trusted source of information for Medicare beneficiaries about how they can get real help from Medicare's new coverage.

Because success with pharmacists is so integral to the success of our Medicare reforms, one of my top priorities has been to bring much more pharmacist expertise and more of a voice for pharmacy into our agency. Since the new Medicare law took effect, we've hired at least one pharmacist in each of our 10 regional offices. And we've added 10 more pharmacists in our central office, including pharmacists in senior leadership positions inside the Center for Beneficiary Choices. People like Kim Caldwell, formerly at the Texas Board of Pharmacy. And within my own immediate office, Larry Kocot is working closely with me to make sure we are bringing these pharmacy perspectives to bear effectively throughout CMS. We've also made arrangements to work with up to 125 additional pharmacists to take a close look at the features of the drug benefit like the drug formularies that have been proposed by the health plans that intend to offer Medicare drug coverage.

CMS is not the agency we used to be – we are increasing our expertise and our ability to support the work of health professionals with our beneficiaries to get the most out of our coverage and our health care system. And the #1 health professional priority at CMS, based how we are acting, is pharmacists. You have the most pharmacist voices inside CMS in the history of Medicare. In our regional offices and our main offices in Baltimore and my very own office, you have a place to turn. And I want to challenge you all to make the most of these opportunities to improve Medicare and our health care system. This is essential, essential for our success in reforming Medicare.

And that brings me to the key barriers we need to overcome, now that we know that the drug coverage is going to be available everywhere, on schedule. Our estimates show that tens of millions Medicare beneficiaries will enroll in Medicare drug plans in the initial months of the drug benefit. And a recent Kaiser Family Foundation survey found that almost one-third of seniors said that they would "very likely turn" to their pharmacists for help with decisions about Medicare drug coverage. This is just plain obvious, since pharmacists were a main place that

beneficiaries turned for the Medicare drug discount card – and for the six and a half million seniors who have enrolled and who are getting billions of dollars in savings, the card has made a big difference.

And it's obvious that we have a far bigger opportunity and challenge with the drug benefit, with even more at stake. It can be the best opportunity ever to show seniors that their pharmacists really are critical, but we have a big challenge to make sure it works when you interact with seniors about the drug benefit. From our work with pharmacists, we know that at least two barriers stand in the way of providing the practical, personalized assistance that seniors expect from their pharmacists: time and information.

Working with you, we're going to do something about those key barriers to the success of the drug benefit. That's why we're using the Medicare law to make significant changes to save pharmacists time so you can spend it with our beneficiaries. And we are also working to give you the information you need to educate beneficiaries to become informed consumers, in a form that is easy for you to use within the constraints of a busy pharmacy.

So I'd like to turn to three big issues now: what CMS is doing to support pharmacists under the new drug benefit; what we're doing to create more time for you to spend with patients; and what we're doing to provide you with the relevant and useful information you need to help beneficiaries get the most out of the new drug coverage.

First, and perhaps most importantly, we are using the new Medicare law to support and protect the critical role of pharmacists in providing care.

Our interactions with you and our own pharmacy experts have made clear how important it is for the success of the drug benefit for beneficiaries to continue to have access to the local pharmacists who they depend on. And so, although while we provide the new benefit through health plans, **the Medicare law and our regulations to implement the law create safeguards to ensure that beneficiaries have access to pharmacies that are conveniently located where they live and work, and where they can maintain the face-to-face relationships with their pharmacists.**

First, as you know, the Medicare law requires that Medicare drug plans meet the TRICARE access standards for pharmacy networks for Department of Defense retirees all over the country. These access requirements can only be satisfied through broad participation of community pharmacies. The new legislation also creates an "any willing provider" requirement for plans participating in the Medicare drug benefit program, and our rules require plans to offer a standard set of contract terms to any willing pharmacy.

Through our final regulation for the drug benefit, CMS has also addressed concerns about creating a “level playing field” for retail and mail-order pharmacies. I want to say unequivocally, in our benefit, Plans cannot force beneficiaries into a choice that may not be best for them through the use of “mandatory mail” programs.

In addition, the Medicare law requires plans to give their enrollees the option of purchasing a 90-day extended supply of a covered Part D drug through a network retail pharmacy, rather than through a network mail-order pharmacy only. To implement this, we have just released further guidance to provide a clear path for retail pharmacies to compete directly with mail order pharmacies, leaving the decision about where to fill prescription where it should be: up to the beneficiary.

To get the most value from the drug benefit, we also want to reward and support the extensive knowledge and real world experience of retail pharmacists for assisting in coordinating and managing drug therapies. Under the law, plans must implement a program of medication therapy management for certain high-risk beneficiaries, in particular, patients with high spending who take multiple drugs for multiple chronic diseases. Now, MTM is growing, there’s some real evidence that it can be a tremendously valuable element of helping seniors get better health outcomes while spending less money, particularly when it comes to chronic diseases. But more evidence on how we can best identify and support truly effective MTM plans is needed. And as you know, like other areas of health care, the quality of pharmacy services can vary considerably. With your help, I think we can find ways to change this, so that pharmacies that really do help patients get better outcomes and lower costs can get the support they deserve – in both public awareness and in payment.

This is actually a top priority for us throughout the Medicare program: for all of the health professionals that we deal with, we want to find better ways to identify and reward the health care providers that do the most to help our beneficiaries get well and stay well at the lowest overall costs of care. For example, we’ve started publishing valid clinical quality measures for virtually every hospital in the country, and we’re also building on systems of public reporting for nursing homes, home health agencies, dialysis facilities and soon, ambulatory care. We’d like to do the same kind of thing for pharmacy care – to recognize and then to reward high-quality pharmacy services. To do this, it is very important to find ways to measure the quality of pharmacy services. And to do that, we need leadership and partnership with the pharmacy community, because measuring and rewarding measure quality only works when health professionals and other stakeholders work together. That’s why we are pleased to partner in privately-led efforts that include health professionals, health plans, business groups, patient advocacy groups, and other key stakeholders for hospital quality initiatives, and nursing home quality initiatives, and now a very promising ambulatory quality

initiative. With all of the promising work to date and the opportunities that the Medicare law presents, this may be the time for a pharmacy quality initiative.

Second, to move beyond providing an opportunity and a path to effective support for high-quality pharmacy care, we need to make it easier for you to work with us. That's why **the second big thing I want to talk to you about is what we're doing to save you time** – time that you need to provide counseling and assistance to patients.

You know the studies that have shown that pharmacists spend at least 25% of their time handling basic insurance functions, like when beneficiary doesn't have their health plan information or know who to bill. That's just not efficient. You can't afford this anymore, and neither can we. Thanks to the new Medicare law, we've got an opportunity to implement new technologies to increase the speed, ease, and accuracy of identifying insurance coverage and filling prescriptions and determining payments.

This includes a new, electronic Coordination of Benefits system that was developed through a public-private partnership which included input from a wide range of pharmacy groups. This new COB support system is designed with one purpose in mind: to make sure that pharmacists don't have to be insurance clerks as well as critical health care providers. This COB system will play a critical role in the electronic exchange of information between CMS and payers, to ensure that beneficiaries get all their available coverage when out-of-pocket costs are charged at the pharmacy.

The result of this COB strategy, which has had an RFP out and for which we are finalizing the contract now to get it implemented ahead of the drug benefit, will be a system that will enable pharmacies and plans to process a beneficiary's prescriptions smoothly, even for that beneficiary who shows up at the pharmacy counter next January and doesn't even remember his drug plan's name. And, the system will enable plans to inform beneficiaries as to when they have reached certain coverage limits, and when they can expect even greater financial relief in the case of catastrophic coverage, and how much they can save with a generic version of their medicine. They will have their claims processed correctly, without the need for bringing in receipts or extra cards or submitting other documentation if they have wraparound coverage.

The goal of this system is to help smooth the transition for beneficiaries and to avoid extra time and effort for pharmacies, providing you with the opportunity to use some of the productivity gain to be invested in time spent helping beneficiaries get the most out of the benefit.

But that's not the only environmental change we're making. We simply we cannot become a 21st century health care system while providers exchange clinical information using 19th century instruments – pen and paper – augmented

by a 20th century technology – overused fax machines to move these paper records around every time they're needed. The Medicare law also gives us the authorities and opportunity to take advantage of effective technologies that should be used now to change this.

The Medicare law requires us to move to e-prescribing. The benefits are obvious. E-prescribing can improve patient safety, quality of care, and administrative efficiencies for physicians and pharmacies. With e-prescribing, pharmacists and other health professionals can get more support in getting the most appropriate, least costly drug for every patient. This will facilitate better decisions about prescription drugs, and that means more for our money in the drug benefit. The law requires widespread implementation of e-prescribing no later than 2009. Well, we're going to accelerate that schedule. We recently published a proposed rule to establish foundation standards for e-prescribing. And we're going to finalize this rule so that the standards are operational before the drug benefit begins in 2006. So, working with companies such as SureScripts and others who are leading the advancement of electronic prescribing, we're building on the existing progress toward electronic health care in pharmacies to ensure the real-time, up-to-date exchange of information to help you better serve your patients.

And that brings me to the third critical topic. With the drug benefit starting in January, and with these new support systems coming into place to help you concentrate on helping seniors with their drug needs, we need to make sure that you have clear information about the drug benefit to share with your patients.

We want to make sure everyone knows the key facts about what is coming. **Enrollment begins on November 15th.** The first enrollment period runs **through May 15, 2006.** Although enrollment is voluntary, **seniors will pay less if they enroll on time.** It's just like homeowners insurance or life insurance – you pay more if you wait.

Our primary message is: **Medicare's new coverage will help seniors pay for the prescriptions they need, regardless of how they pay for drugs now**. Medicare's coverage will help with brand-name and generic drugs, and seniors can get these savings at a retail pharmacy that's convenient for them.

When you talk about the drug benefit, you may want to share not just these basic points but some of the numbers, because the savings will be significant. When our coverage takes effect in 2006, a typical person with Medicare would see Medicare's new coverage pick up more than half of his or her total drug spending, or nearly $1,300. Again, our main task right now is awareness - not all seniors know about the drug benefit, and many mistakenly think it's not a benefit for them.

And for people with limited means, the message is: If you're just living off their Social Security check, you can get even more help. **Medicare's new prescription drug coverage will help all seniors pay for needed prescriptions, but it offers *significant extra help* to beneficiaries with low incomes.**

This is truly comprehensive help for seniors who are struggling between paying for their drugs and for other basic necessities. Seniors who are eligible for Medicare and Medicaid, and those who have incomes below 135 percent of the federal poverty level and limited financial assets – that's an income for a couple of around $18,000 – they will get a Medicare drug benefit that includes no premiums or deductibles whatsoever, no gaps, and copays of just a few dollars. On average, Medicare will be paying over 95 percent of their drug costs. That's a drug benefit worth well over $4,000. And this coverage isn't available only to a few: almost a third of our beneficiaries are eligible. And some extra help is also available for beneficiaries with higher assets and incomes up to 150 percent of the poverty level.

To make sure that all beneficiaries can take advantage of the new assistance that's available to them, it helps to think of beneficiaries as falling into **four main groups** that need different kinds of information and support.

The first group is beneficiaries who have drug coverage now and are satisfied with it, including beneficiaries with retiree coverage and beneficiaries in Medicare Advantage plans. For these beneficiaries, we're working with their employer or union plan, or with their Medicare Advantage plan, to make sure they get the new help and that they know its coming.

The second group is the "full dual eligible" beneficiaries who are eligible for both Medicare and Medicaid and who currently get their drug coverage through Medicaid. For these beneficiaries, we are starting early. We are getting information from states now, so that we can start notifying these beneficiaries and their caregivers about what's coming.

A third group consists of those beneficiaries with relatively higher incomes and assets who don't have adequate coverage today. As I said, we need to make sure these seniors know that the new drug benefit will be available to them, and that they can get specific information on how they can enroll starting this fall to save money and get more financial security.

A fourth critical group of beneficiaries are those with low incomes who are not on Medicaid drug coverage. Now, although we are taking unprecedented steps for the many millions of beneficiaries who really need help to qualify for the comprehensive low-income subsidy, **enrollment in the extra help for lower-**

income beneficiaries is not necessarily automatic. We can identify many of them, such as those with so-called SLMB or QMB benefits, the limited Medicaid benefits, and get them into the comprehensive coverage. But there are millions more beneficiaries who may qualify, and we need to reach out to them to help them complete and submit the subsidy application. And we're making it as simple as possible. The application is only seven pages in large type, with only four pages of actual questions and a total of 16 questions. And no financial documents or other attachments are required. In comparison, the SSI application runs to 28 pages, Medicaid applications are generally 20 or more pages and require financial records, and so forth. The low-income subsidy, or LIS form can be filled out with just a little information on liquid assets and income. So this is easier than it's ever been by far to get means-tested extra help, but it's going to be some work.

And that's why we are starting early. Applications for the low-income subsidy will start being available later this month. The Social Security Administration will be sending out millions of letters to potentially eligible beneficiaries. The idea is to have the maximum amount of time possible to identify low-income beneficiaries and get them enrolled. You can help by making sure that any of your beneficiaries with limited incomes, living just on a Social Security Check with below about $13,000 income for a single and $18,000 for a couple, know to send in the application starting in June. Even if they can only do part, that's ok, we can follow up and help with the rest. The main thing is, get the low-income subsidy application in to Social Security as soon as possible this year.
We're taking new steps to accomplish this goal. Today I am pleased to announce a significant new partnserhip between our nation's pharmacies and CMS, the Social Security Administration (SSA), the Administration on Aging and many advocacy groups.

We are well aware how hard it is to reach this population, even with free, comprehensive benefits. After more than a decade, the SLMB and QMB and SSI program have enrolled less than half of those eligible. But we've learned our lessons from those programs, and I think we can do much better this time, together.

Through the leadership of NCPA and individual pharmacies and their buying groups across the country, we will be launching a community-based program to help Medicare beneficiaries apply for the extra help, using that simplified application developed through the SSA. Beginning early this summer, Medicare beneficiaries will be able to go to a participating pharmacy, or an event sponsored by a participating pharmacy, for information or assistance in completing and filing their SSA application. This is a great outreach step: it is natural that at the place people have to pay for their prescriptions, and where we have the best personal knowledge about which Medicare beneficiaries really need help, that pharmacists are providing this leadership.

We are pleased to have the commitment of our nation's leading independent community pharmacy association, the NCPA, at the forefront of this important application assistance effort. And in addition to the NCPA, I also want to recognize the leadership of specific pharmacy organizations who are stepping up to this challenge. In response to our call to action, the Medicine Shoppe, Medicap and Leader Pharmacies, as well as the national wholesaler, Cardinal Health, have embraced this challenge. Wal-Mart and CVS, the nation's largest pharmacy chain, are already working on their action plans. Additionally, Albertson's, Giant, Stop &Shop and the rest of the Ahold family of supermarket pharmacies among many other pharmacies, small and large, regional and national, are signing on to assist in this effort. In the coming days and weeks, we will be recognizing others who will help and we hope that each of you will as well.

I know Bruce will be speaking with you more about this and there will be more information available throughout the next couple of days from our local outreach partners at SSA and elsewhere in government. In fact, SSA will have a display right outside this room tomorrow, and will be speaking tomorrow morning to explain the application process and to help prepare you for this application drive.

In addition to helping with low income assistance, we are also grateful to NCPA and other pharmacy organizations such as the NCSPAE, for their enthusiasm and commitment to helping Medicare beneficiaries understand this historic new benefit and prepare for the choices they will be able to make about this new drug coverage.

With your help, we are working together to develop a comprehensive campaign to reach out to pharmacists with specific, consistent, and useful information about the drug benefit. Of course, this includes outreach and education and training for pharmacies. Pharmacist education programs are being developed right now, and we need your help to leverage experience, reach, and resources to roll out a comprehensive pharmacist education plan. This program is being designed while keeping in mind on the one hand the pressures and limitations on pharmacists today, while recognizing on the other hand that the Medicare benefit will unquestionably have important impacts on pharmacy services, and effective training on key issues will help make sure that impact is as positive as possible.

As this campaign moves later this year from making people aware to helping people enroll and start saving, there are also going to be many options for supporting confident decisions. Our toll-free phone line,1-800-MEDICARE, is available 24 hours a day, seven days a week, with customer assistance in Spanish as well. And all the information that we provide on the phone is also available through our website, medicare.gov, which has been upgraded and enhanced for ease of use based on your input. We are currently testing Prescription Drug Plan Compare tools, which will be available in the fall with specific information on drug prices and pharmacies and benefits that can be personalized to our beneficiaries' needs.

With all of these steps, we will succeed in helping many more Medicare beneficiaries get much more assistance with their drug costs than ever before. We are going to deliver the drug benefit on time, we are going to make seniors aware, and then we are going to focus on helping seniors enroll so that they can lower their medical costs significantly. Enrollment is the bottom line, because that's what leads to lower drug costs. Awareness now, then assistance, then enrollment starting later this year for all of our beneficiaries – and as you just heard, applying for extra assistance starting in a big way this month thanks to your help.

So we've started some important collaborations with pharmacies all over the country – from the big chains to the small, independent shops and everything in between. These partnerships are critical: seniors place a great deal of trust in the pharmacist, so it's vital that Medicare work with you and give you up-to-date information to share with your patients so they can make the most of the drug coverage coming available in 2006. And that's why I'm so glad NCPA is doing so much to take the lead, providing the expert partnership we need for the effective delivery of new pharmacy benefits. We face some real challenges. But I'm confident we will meet them, together, to bring longer life and better health through affordable, modern health care to every one of our citizens. Thank you.

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